5. 510(k) Summary of safety and effectiveness

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

APPLICANT:	MPS Acacia
TRADE NAME:	Power Injectable Infusion Set
COMMON NAME:	IV Extension Set
CLASSIFICATION NAME:	Intravascular Administration Set
DEVICE CLASSIFICATION:	Class II
PRODUCT CODE	FPA
PREDICATE DEVICES:	MPS Acacia Safeguard Huber Device (K032934) SafeStep Max Power Injectable Infusion Set (K073050) Medegen Pressure Rated Extension Set (K083472)

APR 2 8 2009

Substantially Equivalent To:
The MPS Acacia Power Injectable Infusion Set is substantially equivalent in intended use, principal of operation and technological characteristics to the MPS Acacia Safeguard Huber Needle Device (K032934), the SHPI SafeStep Max Power Injectable Infusion Set (K073050), and the Medegen Pressure Rated Extension Set (K083472).

Description of the Device Subject to Premarket Notification:
The Power Injectable Infusion Set, consists of a female luer lock, non-DEHP PVC tubing, on/off clamp, and either a male luer lock for connection to female hub central venous catheters or Huber needle for insertion into implanted port catheters.

The Power Injectable Infusion Set will be provided as a sterile, single use, non-pyrogenic, disposable device and will be available in a variety of lengths and sizes.

Indications for Use:

The Power Injectable Infusion Set with Huber Needle is indicated for:

- Use with implanted infusion ports for continuous or intermittent infusion therapy.
- Infusion or withdrawal of IV fluids, blood, blood products, or drugs.
- Use with ports that are indicated for power injection of contrast media into the central venous system. For power injection of contrast media, the maximum recommended infusion rate is 5mL/sec. for 19 gauge and 20 gauge needles, and 2mL/sec. for 22 gauge needles.
- Power injection of contrast media up to 325 PSI.

The Power Injectable Infusion Set with male luer lock is indicated for:

- Use with central venous catheters for continuous or intermittent infusion therapy.
- Infusion or withdrawal of IV fluids, blood, blood products, or drugs.
- Use with central venous catheters that are indicated for power injection of contrast media into the central venous system.
- Power injection of contrast media up to 325 PSI.

SECTION 5 510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

Technical Characteristics:

The Power Injectable Infusion Set has similar physical and technical characteristics to the predicate devices.

Performance Data:

All necessary verification and validation testing has been performed for the Power Injectable Infusion Set to assure substantial equivalence to the predicate devices.

Basis for Determination of Substantial Equivalence:

Upon reviewing the safety and efficacy information provided in this submission and comparing intended use, principle of operation and overall technological characteristics, the Power Injectable Infusion Set is determined by MPS Acacia, to be substantially equivalent to the existing legally marketed devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MPS Acacia
C/o Mr. Mark Job
Reviewer
Regulatory Technology Services, LLC
1394 25th Street, NW
Buffalo, Minnesota 55313

APR 2 8 2009

Re: K090809
Trade/Device Name: MPS Acacia Power Injectable Infusion Set
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: II
Product Code: FPA
Dated: April 16, 2009
Received: April 20, 2009

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements

of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Anthony D. Watson for

Susan Runner, D.D.S., MA
Acting Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K090809

Device Name: MPS Acacia Power Injectable Infusion Set

Indications for Use:

The Power Injectable Infusion Set with Huber Needle is indicated for:

- Use with implanted infusion ports for continuous or intermittent infusion therapy.
- Infusion or withdrawal of IV fluids, blood, blood products, or drugs.
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The Power Injectable Infusion Set with male luer lock is indicated for:

- Use with central venous catheters for continuous or intermittent infusion therapy.
- Infusion or withdrawal of IV fluids, blood, blood products, or drugs.
- Use with central venous catheters that are indicated for power injection of contrast media into the central venous system.
- Power injection of contrast media up to 325 PSI.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K090809